K092749

510K SUMMARY

DEC - 3 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92

The assigned 510(k) number is: TBD

COMPANY/CONTACT PERSON

Lisa Charter
Manager, Regulatory Affairs
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DATE PREPARED

August 30, 2009

DEVICE NAME

Trade Names:
MAS® PTH Control
Moni-Trol® PTH Control

Common Names:
Liquid Assayed PTH Control

Device Classification: Class I

Classification Panel: Quality Control Material (Assayed and Unassayed) for Clinical Chemistry

Regulation number: 21 CFR 862.1660

Product Code: JJX

INTENDED USE:

MAS® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

Moni-Trol® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

SUBSTANTIALLY EQUIVILANT PREDICATE DEVICE

MAS® PTH Control Moni-Trol® PTH Control is substantially equivalent to the previously cleared Liquichek ™ Specialty Immunoassay Control (K043108)

DESCRIPTION OF DEVICE

This product is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or bodily fluids. Preservatives and stabilizers are added to maintain product integrity.

Comparison of Technological Characteristics

Comparison	Predicate Device, K043108	Proposed new device
Intended Use	For use as quality control serum to monitor the precision of laboratory testing procedures listed in the package insert.	MAS® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument. Moni-Trol® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations.

		Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.
Description of device	This product is prepared from human serum with added constituents, chemicals, stabilizers, and preservatives.	This product is a liquid stable control material prepared from human serum. Analyte levels are adjusted with various pure chemicals and preparations from human tissue or bodily fluids. Preservatives and stabilizers are added to maintain product integrity.
Matrix	Human Serum	Human Serum
Form	Liquid	Liquid
Storage Condition	-20°C to -70°C until expiration date on the label	-25°C to -15°C until expiration date on the label
Open Vial Stability	30 days at 2-8°C with exceptions	30 days when stored tightly capped at 2-8°C
Closed Vial Stability	30 days at 2-8°C with exceptions	90 days when stored tightly capped at 2-8°C
Analytes	Anti-Tg Anti-TPO C-Peptide Erythroprotein Intact PTH IGF-I Osteocalcin 25-OH Vitamin D	PTH

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center-WO66-G609
Silver Spring, MD 20993-0002

DEC 3 2009

Microgenics Corporation
c/o Ms. Lisa Charter
Manager, Regulatory affairs
Thermo Fisher Scientific
Specialty Diagnostics Division, CDx Fremont
4630 Fremont Blvd.
Fremont, CA 94538

Re: k092749
Trade/Device Name: MAS® PTH Control and Moni-Trol® PTH Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: September 04, 2009
Received: September 08, 2009

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807);

labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K092749

Device Name:

MAS® PTH Control
Moni-Trol® PTH Control

Indication For Use:

MAS® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

Moni-Trol® PTH Control is intended for use in the clinical laboratory as a consistent test sample of known concentration for monitoring assay conditions in many Parathyroid hormone (PTH) determinations. Include PTH Control with patient serum specimens when assaying for Parathyroid hormones. Assay values are provided for the specific systems listed. The user can compare observations with expected ranges as a means of assuring consistent performance of reagent and instrument.

Prescription Use ___x___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Maria M Chan

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K092749